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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,078	04/25/2001	Olivier De Lacharriere	016800-438	6852

7590

05/14/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,078

Applicant(s)

LACHARRIERE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-18 are pending. The Amendment received December 20, 2001, amended claims 1 and 2.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed December 20, 2001 (Paper No. 3) to the rejection of claims 1-18 made by the Examiner under 35 USC 102 and 103 have been fully considered and deemed not persuasive.

The Applicant's arguments filed December 20, 2001 are sufficient-in-part to overcome the rejection under the judicially created doctrine of double patenting. See below for details.

The Applicant's arguments and amendment filed December 20, 2001 are sufficient-in-part to overcome the 35 USC 112 rejection. See below for details.

Double Patenting Rejection Maintained

The rejection of claims 1-18 under the judicially created doctrine of double patenting as being unpatentable over claims 1-7 of 5,658,531 and over claims 15-41 of 6,060,061 is MAINTAINED for the reasons set forth in the Office Action mailed September 20, 2001, Paper No. 2, and those found below.

Applicant states that terminal disclaimers have been filed. However, the Office has not received any terminal disclaimers.

112 Rejection Maintained

The rejection of claims 1, 10 and 11 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed September 20, 2001, Paper No. 2, and those found below.

(i) The rejection of the term “solvents” in claim 11 is maintained. Applicant argues that claim 11 has been amended to remove the word “solvents”. However, claim 11 has not been amended.

(ii) Claim 1 is rejected because the compounds in this claim are not defined with any chemical or physical characteristic, but only by functional properties. A claim to a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed invention. Thus, the scope is indefinite. See *ex parte Pulvari* (POBA 1966) 157 USPQ 169.

(ii) The rejection of the term “one agent which produces an irritant side-effect” in claim 10 is maintained. Applicant argues that claim 10 has been amended to remove the term. However, claim 10 has not been amended.

102 Rejection Maintained

The rejection of claims 1-2, 5-8, 10-11 and 14-17 under 35 U.S.C. 102(b) as being unpatentable over Parker et al. (5,039,695) is MAINTAINED for the reasons set forth in the Office Action mailed September 20, 2001, Paper No. 2, and those found below.

Applicant argues, “Parker discloses that the compound of formula I can be administered with a pharmaceutically acceptable carrier using conventional dosage unit forms. . . Additionally, Parker discloses that the disclosed compositions can be preserved by adding an antioxidant. . . In stark contrast, the composition of the presently claimed invention, requires a combination of at least one IL-1 antagonist and/or at least one TNF-alpha antagonist and at least one active agent that elicits a desired effect in the composition”. This argument is not persuasive. The Examiner respectfully points out that a compound and its properties are inseparable (*In re Papesch*, 315

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F.2d 381, 137 USPQ 43, CCPA 1963). Since Parker et al. teach the same constituents in similar percent weights as that of the instant invention, this argument is not persuasive.

Applicant argues, "The composition of the presently claimed invention further requires that the active agent be contained in an amount sufficient to cause irritation. . .the presently claimed invention includes specific amounts of both IL-1 antagonist and/or TNF-alpha antagonist and active agent". This argument is not persuasive. First, the argument is not commensurate in scope with independent claim 1, as the claim does not recite specific amounts, but describes amounts with functional language. Furthermore, Parker teaches amounts of the IL-1 antagonist within the range cited by Applicant. See Example 7 of Parker and instant claim 5.

Applicant argues, "nowhere does Parker specifically disclose or suggest a composition comprising an active agent that elicits an irritant side-effect to a user of the composition". This argument is not persuasive. The Examiner respectfully reminds the Applicant that a compound and its properties are inseparable, and in the instant case, cetyl alcohol is an agent that elicits an irritant side-effect, as it is both an organic solvent and an alcoholic solution. The Examiner respectfully directs the Applicant to page 15, [0061] of the specification, wherein irritant agents are defined.

Applicant argues, "Accordingly, Applicants submit that the composition of Parker would not include the specific ratio of irritant relative to IL-1 antagonist and/or TNF-alpha antagonist, as claimed". This argument is not persuasive, as it is not commensurate in scope with the instant claims, as the instant claims do not recite ratios.

103 Rejection Maintained

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The rejection of claims 1-18 under 35 U.S.C. 103(a) as being unpatentable over Parker et al. in view of Blank et al. (5,605,894) is MAINTAINED for the reasons set forth in the Office Action mailed September 20, 2001, Paper No. 2, and those found below.

The Examiner respectfully points out that this rejection combined the teachings of Parker et al. and Blank et al. However, Applicant has argued against the references individually. In response to applicant's arguments against the references individually, the Examiner respectfully points out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

103 Rejection Maintained

The rejection of claims 1-18 under 35 U.S.C. 103(a) as being unpatentable over Blank et al. (5,605,894) in view of Skotnicki (4,902,800) is MAINTAINED for the reasons set forth in the Office Action mailed September 20, 2001, Paper No. 2, and those found below.

The Examiner again respectfully points out that this rejection was based on the combination of Blank and Skotnicki. However, Applicant has argued against the references individually.

The Examiner respectfully points out that Blank and Skotnicki are both directed to compositions comprising inflammatory active agents for treating skin conditions. It is respectfully pointed out that it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980).

Specification

The amendment filed December 20, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the substitution of the term "overheating" for "inflammation" in paragraphs 7, 11-13, 20, 24 and 26, is new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, there are no unexpected results.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 7, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200